

REMARKS

Status of the Claims

Claims 3, 41 and 42 are pending in this application. Claims 1-2 and 4-40 have been canceled. Applicants preserve the right of filing a divisional application directed to the non-elected invention at a later stage.

Interview Summary Record

A first interview was conducted with the Examiner on September 9, 2004, to clarify the Examiner's intent in the first three lines on page 3 of the Office Action, which reads as follows:

In the case Seq ID NO. 72 and the amino acid encoded by SEQ ID No. 36 that may be produced as final products have identified substantial utilities.

Applicants' Representative requested clarification and confirmation that a claim limited to an amino acid sequence according to SEQ ID NO:72 and to amino acids encoded by the isolated nucleic acid sequence of SEQ ID NO:36 would overcome the utility related rejections on pages 2-6 of the Office Action. The Examiner indicated that she would review the application and then call Applicants' Representative later in the day with her comments.

After reviewing Applicants' proposal, the Examiner indicated that the abovementioned passage contained a typographical error and should read as follows:

In the case Seq ID NO. 72 and the amino acid encoded by SEQ ID No. 36 that may be produced as final products have no identified substantial utilities. [emphasis added by the undersigned]

Applicants' Representative subsequently presented arguments as to why the utility related issues should be withdrawn. The Examined requested that these arguments be submitted in Declaration form and that they would be considered when she reconsiders the above-mentioned utility related rejections referred to above.

Applicants' Representative also pointed out that Applicants' proposed amendments to claim 3 and cancellation of claims 13, 14, 15, 17 and 18 should fully address the written description rejection [pages 7-8 of the Office Action] and enablement rejections [pages 9-11 of the Office Action].

Moreover, Applicants' Representative pointed out that rewriting claim 3 so that it does not depend on claim 1 renders moot the rejection under 35 U.S.C. 112, second paragraph on page 11 of the Office Action.

Rejection of Claims 3, 4, 13(in-part), 15 and 17 Under 35 U.S.C. §101/112 (Pages 1-6 of Office Action)

Claims 3, 4, 13(in-part), 15 and 17 have been rejected by the Examiner under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility. Claims 3, 4, 13(in-part), 15 and 17 have been rejected by the Examiner under 35 U.S.C. 112, first paragraph,

because one skilled in the art would not know how to use the claimed invention because the claimed invention is not supported by either a substantial asserted utility or a well-established utility. These rejections are respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Present Invention

The present invention as recited in claim 3 relates to an amino acid sequence selected from the group consisting of:

- (ii) an amino acid sequence coded by the isolated nucleic acid sequence of SEQ ID NO:36: and
- (ii) and amino acid sequence according to SEQ ID NO:72.

Accordingly, the invention has been limited to an amino acid sequence coded by the isolated nucleic acid sequence of SEQ ID NO:36 or to an amino acid sequence according to SEQ ID NO:72.

Response to Rejection

The Examiner should note that the nucleic acid sequence of SEQ ID NO:36 corresponds to NV-36. Further, the Table starting on page 23 of the specification clearly identifies the function of the variant NV-36 under examination, that is, the amino acid sequence of SEQ ID NO 72 or nucleic acid sequence of SEQ ID NO 36. In the Table, the variants are listed in the same order as the sequences provided in the sequence listing. Therefore, it is clear that NV-

36 corresponds to SEQ ID NO 36.

Further, the Table clearly shows that NV-36 is a variant of KPCT_HUMAN, and that *"the new variant has an alternative 3' exon of 36 amino acids instead of 94 original amino acids. The alternative region is in the PROTEIN KINASE domain. The new variant maintains the two PHORBOL-ESTER AND DAG BINDING domains, the two ATP binding sites and the ACTIVE of the KINASE domain"*. KPCT_HUMAN is a known protein; for example, entering this information to the SwissProt database (for which KPCT_HUMAN identifies the record of this protein) results in a complete description of this protein being provided.

The known protein is Protein Kinase C (PKC), theta type, which phosphorylates a wide variety of proteins when activated. PKC is also involved as an oncogene; for example, it can be activated by a group of chemicals called phorbol esters, which are known tumor promoters. This information is also provided further in the text of the present application.

Both textual and graphical descriptions of the domains of PKC are provided in this record. These descriptions enable one of ordinary skill in the art to easily understand the description of the NV-36 variant according to the present invention.

Since the variant has a different protein kinase domain, but otherwise maintains the other domains of PKC, it is expected that protein kinase activity is affected but not abolished, since the

active site of the protein kinase domain is still present.

Figure 36 shows the alignment of the known PKC sequence and of the sequence of the NV-36 variant according to the present invention, showing the differences between the sequences.

The utility of the NV-36 variant is therefore clearly linked to the similarity/differences between this protein and the known PKC (theta) protein. As noted above, the variant protein differs in the kinase domain (while still having the active site), and therefore could be used to study the structure of this domain and its function, for example. Such information would clearly be useful for developing new drugs that could modulate PKC activity and/or activity of other kinases. Such utility is proposed in the present application.

Furthermore, the NV-36 variant could also be useful for studying the location and function of these proteins as oncogenes vs. their desired physiological activities; for example, PKC (theta) is highly expressed in hematopoietic cells, such that the NV-36 variant could be useful for studying both blood cancers and also the genesis of blood cells. The former activity is clearly non-desirable, while the latter activity is desirable, such that the NV-36 variant could be useful to understand and interpret the differences between these activities. PKC (theta) is present in platelets, which also have both desirable and potentially pathological activities, depending upon other factors in the body;

NV-36 could also be useful for an understanding of the differences between these different activities.

The Bork reference mentioned by the Examiner on page 4 of the Action is not contradictory to the above statements. Bork refers to overall statistical probability for sequence comparison. However, the degree of reliability of sequence/function data for different proteins clearly depends upon the degree to which they have been studied. Proteins that have been well studied and characterized, particularly those belonging to well-characterized protein families, clearly have more reliable associated functional and structural data. Protein kinases, especially those belonging to the protein kinase C family, are exceptionally well studied and characterized proteins. For example, protein kinases have their own publicly available database, called Kinbase (available at <http://198.202.68.14/>), which shows that a large amount of information has been collected about such kinases throughout a wide variety of organisms. These kinases have been subjected to extensive analyses. The PKC family itself is of great interest to researchers, because of its known involvement in a wide variety of intracellular signalling pathways and also because of its involvement in various cancers. For example a search of PubMed with the term "PKC" turned up 17997 references. Thus, the Bork reference is not relevant to the particular case of PKC and the NV-36 variant of the present invention, because of the extensive

studies that have been performed on the PKC family.

Similarly, general statements of uncertainty regarding protein chemistry are not applicable to the PKC family for the above reasons.

Thus, the NV-36 variant of the present invention clearly has utility, which is well expressed in the present application. Furthermore, as the above statements clarify, the present application also provides a clear description of how to use the NV-36 variant according to the present invention, thereby overcoming the rejections under 35 U.S.C 101/112.

Rejection of Claims 3, 4, 13(in-part), 15, 17 and 18 Under 35 U.S.C. §112, First Paragraph (Pages 7-8 of Office Action)

Claims 3, 4, 13(in-part), 15, 17 and 18 have been rejected by the Examiner under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Claim 3 has been amended to more specifically define that the amino acid sequence is a sequence selected from the group consisting of: (i) an amino acid sequence coded by the isolated nucleic acid sequence of SEQ ID NO:36; and (ii) an amino acid sequence according to SEQ ID NO:72. Claims 13(in-part), 15 and 17 have been cancelled. As indicated above, this rejection is moot in

view of the amendments to claim 3. Thus, the rejection should be withdrawn.

Rejection of Claims 13(in-part), 15, 17 and 18 Under 35 U.S.C. §112, First Paragraph (Pages 9-11 of Office Action)

Claims 13(in-part), 15, 17 and 18 have been rejected by the Examiner under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This rejection is moot in view of the cancellation of claims 13, 15, 17 and 18.

Rejection of Claims 3, 4, 13(in-part), 15, 17 and 18 Under 35 U.S.C. §112, Second Paragraph (Page 11 of Office Action)

Claims 3, 4, 13(in-part), 15, 17 and 18 have been rejected by the Examiner under 35 U.S.C. 112, second paragraph, because claim 3 depends upon a non-elected claim. This rejection is moot in view of the amendment rewriting claim 3 in independent form and in view of the cancellation of claims 13, 15, 17 and 18.

Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Marc S. Weiner (Reg. No. 32,181) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three month extension of time for filing a reply in connection with the present application, and the required fee of \$475.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 

Marc S. Weiner, #32,181

P.O. Box 747

Falls Church, VA 22040-0747

(703) 205-8000

MSW/sh
2786-0168P